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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,100	10/25/2006	Immanuel Straub	516/12	6349
27538 7590 04/28/2009 GIBSON & DERNIER L.L.P. 900 ROUTE 9 NORTH SUITE 504 WOODBIDGE, NJ 07095				
EXAMINER				
EASTWOOD, DAVID C				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
04/28/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,100

Applicant(s)

STRAUB, IMMANUEL

Examiner

DAVID EASTWOOD

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23 and 24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-21, 23 and 24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed on 3/04/2009. Claims 22 and 25 have been canceled without prejudice. Claims 1-21 and 23-24 are pending and an action on the merits is as follows

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
-
1. Claims 1-2, 5-13, 18, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511).

Regarding Claim 1, Straub et al discloses *a working head that is axially displaceable over a guide wire, is displaceable independently of the guide wire, is arranged at a distal end of the catheter and has at least one lateral opening.* (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16) *a flexible transport screw that has a distal and a proximal part and is capable of being rotated by means of a rotary drive of a drive unit the rotary drive being a distance away from the working head* (Column 3 Lines 65-67 and Column 4 lines 1-8) (Figure 2 and 3 item 24) *a flexible tube surrounding the transport screw, connected to the working head and intended for removing the removable material or detached thrombi and emboli fragments.* (Column 3 lines 19-30) (Figure 1 item 22 and 12) *the transport screw cooperates with the lateral opening of the working head for shearing and comminuting materials or aspirated and/or detached thrombi and emboli penetrating between the peripheral borders of the transport screw* (Column 4 Lines 15-30), and *a tube comprising a proximal part comprising a plastic tube.* (Column 4 Lines 55-56)(Figure 1 item 22).

Straub Fails to disclose *a distal part comprising a metallic helical spring having a thin-walled elastic plastic sheath.*

However, Kocak discloses a flexible tube for intravenous use comprising a helical coiled spring throughout (Figure 6)(Abstract Line 3-9)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the helical metallic spring and sheath as taught by Kocak. Doing so would provide a flexible support structure for the tube.

Regarding Claim 2, Straub et al discloses *a catheter, a distal and a proximal end, a working head that is axially displaceable over a guide wire independently thereof, and is arranged at the distal end of the catheter, and has at least one lateral opening.* (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16) *a flexible transport screw that has a distal and a proximal part, extends from the proximal to the distal end of the catheter, and is capable of being rotated by means of a rotary drive of a drive unit, the rotary drive being a distance away from the working head, and the transport screw being provided with transport surfaces that extend helically along a longitudinal axis of the transport screw and in a direction of radii of the transport screw* (Column 3 Lines 65-67 and Column 4 lines 1-8) (Figure 2 and 3 item 24) *a flexible tube surrounding the transport screw, connected to the working head and intended for removing the removable material or the-detached thrombi and emboli fragments.* (Column 3 lines 19-30) (Figure 1 item 22 and 12) *the transport screw in the region of the working head cooperates with the cutting tool and the lateral opening of the*

working, in an operating state, to shear, continuously comminute the material or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw and borders of the lateral openings and remove them along the transport surface in a direction of the proximal end (Column 4 Lines 15-30 and line 40 to 51) and a flexible tube comprising a proximal part comprising a plastic tube. (Column 4 Lines 55-56)(Figure 1 item 22).

Straub fails to disclose a distal part comprising a metallic helical spring having a thin-walled elastic plastic sheath.

However, Kocak discloses a flexible tube for intravenous use comprising a helical coiled spring throughout (Figure 6)(Abstract Line 3-9)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the helical metallic spring and sheath as taught by Kocak. Doing so would provide a flexible support structure for the tube.

Regarding Claim 5, Straub et al discloses *the distal part of the transport screw in the region of the working head is formed so as to be an exact fit in the external diameter relative to the internal diameter of substantially cylindrical working head, so that the external diameter of the transport screw has only minimal diameter play relative to the internal diameter of an inner lateral surface of the working head.* This limitation is mandatory in order to form a shearing surface between said transport screw and open slot in said working head (Column 4 Lines 23-30) (figure 6 items 32, 14a and 16)

Regarding Claim 6, Straub et al discloses *the edges on an outside of the transport screw are formed so as to be sharp in a region of the lateral opening of the working head* (Column 4 Lines 23-30)

Regarding Claim 7, Straub et al discloses *the working head tapers towards its distal end*. (Figure 2 item 16f)

Regarding Claim 8, Straub et al discloses *the edges of the lateral opening are formed so as to be sharp at least in sections in a region of an inner lateral surface of the working head*. (Column 4 Lines 23-30)

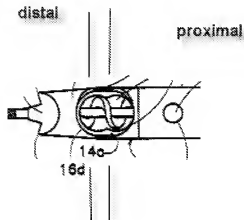
Regarding Claim 9, Straub et al discloses *edges of the lateral opening are formed so as to be rounded at least in sections in a region of the-an outer lateral surface of the working head* (Figure 2 and 3 item 16 c and d)

Regarding Claim 10, Straub et al discloses *the lateral opening is in the form of a slot* (Figure 2 and 3)

Regarding Claim 11, Straub et al discloses *the slot runs at least partially in the-an axial direction of the working head*. (Figure 3 item 14a)

Regarding Claim 12, Straub et al discloses *the slot is formed, relative to a longitudinal axis of the working head, at least partly along a helix* (Figure 3 item 16 and 32)

Regarding Claim 13, Straub et al discloses *a width of the slot decreases toward a proximal end of the working head* (Figure 3 item 14a and 16d)



Regarding Claim 18, Straub et al discloses the working head is connected to the tube axially in a manner resistant to tension and pressure. (Column 4 lines 57-62)

Regarding Claim 23, Straub et al discloses *the working head and/or the transport screw comprise metal, including stainless steel.* (Column 4 Lines 52-56)

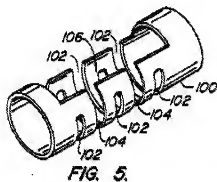
Regarding Claim 24, Straub et al discloses *the working head comprises sintered ceramic; or metal ceramic or has a highly resistant layer, for protection from wear.* (Column 4 Lines 53-55)

3. Claim 3-4, 14 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511) as applied to claim 1 above and further in view of Evans et al (US 5312425).

Regarding Claim 3, the combination of Straub et al and Kocak discloses the claimed invention except for *the lateral opening of the working head forms an L-shaped*

slot having a limb extending substantially in the longitudinal direction and a limb extending along a part of circumference.

However Evans et al discloses a elongate guide frame which axially surrounds a cutting screw which form an L-shaped slot in the opening with a limb extending in the longitudinal direction an a limb extending along the circumference. (Figure 5)



item 102: Circumference limb of L-shaped slot
item 106: Longitudinal limb of L-shaped slot

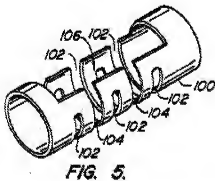
It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the L-shaped slot opening as taught by Evans et al. Doing so would create a larger cutting surface allowing the instrument to more efficiently remove undesired matter.

Regarding Claim 4, the combination of Straub et al and Kocak disclose the claimed invention except for a *ratio of a width of the limb extending in the longitudinal direction to a width of the limb extending in along the part of the circumference direction is from 1.0 to 1.3*

It would have been an obvious matter of design choice to manufacture the open L-shaped slot with *a ratio of a width of the limb extending in the longitudinal direction to a width of the limb extending in along the part of the circumference direction is from 1.0 to 1.3*, since such a modification would have involved a mere change in the size of a component, the open L-shaped slot. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Regarding Claim 14, the combination of Straub et al and Kocak disclose the claimed invention except for *the lateral opening of the working head forms an L-shaped slot having a limb extending substantially in the longitudinal direction and a limb extending along a part of circumference*.

However Evans et al discloses a elongate guide frame which axially surrounds a cutting screw which form an L-shaped slot in the opening with a limb extending in the longitudinal direction an a limb extending along the circumference. (Figure 5)



item 102: Circumference limb of L-shaped slot
item 106: Longitudinal limb of L-shaped slot

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the L-shaped slot opening as taught by Evans et al. Doing so would create a larger cutting surface allowing the instrument to more efficiently remove undesired matter.

Regarding Claim 25, Straub et al discloses *a catheter(12), a distal and a proximal end, a working head that is axially displaceable over a guide wire(24) independently thereof, and is arranged at the distal end of the catheter, and has at least one lateral opening.* (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16)

4. Claim 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511) as applied to claim 1 above, and further in view of Sjostrom (US 2003/0114875).

Regarding Claim 15, the combination of Straub et al and Kocak discloses the claimed invention except for *a distal end region of the working head: at least one groove like starting from the distal end and opening in-to the lateral opening, is arranged on the-an outer lateral surface*

However, Sjostrom discloses a groove-like recess starting from the distal end of a working end and opening into the lateral opening (Figure 8 item 337)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the distal groove in the distal end

traveling toward the proximal end as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

Regarding Claim 16, the combination of Straub et al and Kocak discloses the claimed invention except for a *depth of the groove-like recess increases toward a proximal end of the working head*.

However, Sjostrom discloses a groove-like recess that increases in depth as it travels toward the proximal end. (Figure 8 item 337)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the distal groove which increases in depth as it travels toward the proximal end as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

Regarding Claim 17, the combination of Straub et al and Kocak discloses the claimed invention except for a *width of the groove-like recess is greater than a chord of the internal diameter of the working head in a region of a groove base*

However, Sjostrom discloses a grooved recess which has a diameter greater than the diameter of a chord of the inner diameter of the working head. (Figure 7 item 125)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the larger diameter distal groove as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

5. Claims 19-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511) as applied to claim 1 above, and further in view of Cohen (US 6217565).

Regarding Claim 19, the combination of Straub et al and Kocak discloses the claimed invention except for *the tube has a reinforcement in one or more sections*.

However, Cohen discloses a reinforced catheter tube (abstract line 1)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Stroub et al with the reinforced catheter as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

Regarding Claim 20 the combination of Straub et al and Kocak discloses the claimed invention except for *the reinforcement is in the form of a metallic helix*.

However, Cohen et al discloses a metallic wire reinforcement braid (Column 4 lines 62-67)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the braided/helical mesh reinforcement as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

Regarding Claim 21, the combination of Straub et al and Kocak discloses the claimed invention except for *the reinforcement is arranged on an inside of the tube*

However, Cohen et al discloses the reinforcement on an inside of the tube.
(Figure 1 and 2 item 14)

It would have been obvious to modify the invention of Straub et al with the internally reinforced tube as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

Response to Arguments

2. Applicant's arguments filed 03/04/2009 have been fully considered but they are not persuasive. Applicant argues that the combination of Straub in view of Kocak is improper because of the process of manufacturing the resultant structure.

However, it is noted that the invention of Straub as modified by Kocak appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/26/09